NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC., et al.,** **Defendants.**	**Civil Action No. 17-6921 (MAS)** **MEMORANDUM OPINION FILED UNDER TEMPORARY SEAL**

BONGIOVANNI, United States Magistrate Judge

This matter comes before the Court upon Defendants Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc.'s (collectively, "Teva") letter application seeking leave to amend Teva's non-infringement contentions. (Docket Entry No. 69). Plaintiff Merck Sharp and Dohme Corp. ("Merck") opposes Teva's application. For the reasons that follow, Teva's application to amend its non-infringement contentions is DENIED.

I. Background

As the facts are well-known to the parties and the Court, they are not set forth at length herein. Instead, only those facts related to the instant application are shared.

Pursuant to the schedule set by the Court, Teva's non-infringement contentions were to be served by March 2, 2018. Claim construction discovery was to be completed by July 27, 2018. The parties were to substantially complete their document production by September 14, 2018 and fact discovery was to close on November 7, 2018. *See* Letter Order of 1/3/2018 at 1-3; Docket Entry No. 34. Teva served its non-infringement contentions on March 2, 2018 as required by the Court's Order. The parties also acted in accordance with the other deadlines set by the Court,

though, recently, the Court extended the deadline for the completion of the depositions of fact witnesses previously noticed by the parties from November 7, 2018 to January 16, 2019.

Teva first approached Merck about amending its non-infringement contentions on November 20, 2018, the day after it received the final transcript of Dr. Schmidt's deposition. Dr. Schmidt is one of the inventors of the patent-in-suit, U.S. Patent No. 6,469,030 (the "'030 patent") and his deposition occurred on November 14, 2018. Teva provided Merck with a draft of its proposed amended non-infringement contentions at that time. Merck required time to review Teva's proposed amended non-infringement contentions before it could determine whether it would consent to same. In light of the fact that it received Teva's proposed amended non-infringement contentions two days prior to Thanksgiving, Merck suggested that the parties meet and confer on November 29, 2018. On November 29, 2018, Merck informed Teva that it would not consent to its proposed amendments. As a result, Teva raised the issue with the Court on December 3, 2018. (*See* Letter from Liza M. Walsh to Hon. Tonianne J. Bongiovanni of 12/3/2018; Docket Entry No. 69).

Teva seeks to amend its non-infringement contentions "to present a single, new basis for non-infringement in light of recent discovery showing that the sole asserted claim of the only patent-in-suit does not cover the active ingredient used in the accused ANDA product (alvimopan)." (*Id*. at 1). Specifically, Teva seeks "to add a non-infringement defense that the active ingredient in its proposed drug product (alvimopan dihydrate) does not infringe the only asserted claim in this case–claim 17 of the '030 patent." (Letter from Liza M. Walsh to Hon. Tonianne J. Bongiovanni of 12/10/2018 at 1; Docket Entry No. 74). While Teva contends that its proposed amendment "will not impact the case schedule" (Letter from Liza M. Walsh to Hon. Tonianne J. Bongiovanni of 12/3/2018), Merck disagrees arguing that not only would fact

discovery have to be extended, but Merck's infringement contentions would have to be amended, *Markman* proceedings relating to the scope of Claim 17 of the '030 would have to take place and additional expert discovery would be required. (*See* Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 12/10/2018 at 13; Docket Entry No. 72).

II. Analysis

A. Legal Standard

This District's Local Patent Rules govern Teva's application to amend its non-infringement contentions. "The Local Patent Rules 'exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.'" *King Pharm., Inc. v. Sandoz Inc.*, Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007) (internal quotation marks and citation omitted). Indeed, they "'are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.'" *Id*. (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C 95-1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). As such, unlike proposed amendments of the pleadings, which are liberally granted pursuant to FED.R.CIV.P. 15, amendments to non-infringement contentions are governed by the more conservative standard set forth in L.Pat.R. 3.7. *See Id*. (noting that "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction." (Internal quotation marks and citation omitted)). Thus, while L.Pat.R. 3.7 certainly "is not a straitjacket into which litigants are locked from the moment their contentions are served," the "modest degree of flexibility" that it provides to amend "at least near the outset[,]" must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish

their contentions early on. *Comcast Cable Communs. Corp., LLC v. Finisar Corp.*, No. C 06-04206 WHA, 2007 U.S. Dist. LEXIS 98476, at *5 (N.D. Cal. March 2, 2007).

As noted, Local Patent Rule 3.7 governs amendments of non-infringement contentions. Pursuant to L.Pat.R. 3.7, "[a]mendment of any contentions . . . may be made only by order of the Court upon a timely application and showing of good cause." L.Pat.R. 3.7 sets forth a "[n]on-exhaustive" list of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause" necessary to support the requested amendment. L.Pat.R. 3.7(b) (Emphasis added). Under L.Pat.R. 3.7, good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *Acer, Inc. v. Tech. Prob. Ltd.*, Case No. 5:08-cv-00877 JF/HRL, Case No. 5:08-cv-00882 JF/HRL, Case No. 5:08-cv-05398 JF/HRL, 2010 U.S. Dist. LEXIS 142472, at *3 (N.D. Cal. Sept. 10, 2010) (citing *O2 Micro Intl'l Ltd. v. Monolithic Power Sys., Inc.* 467 F.3d 1355, 1366-68 (Fed. Cir. 2006)). Importantly, absent a showing of diligence, the Court does not reach prejudice. *See Warner Chilcott Co., LLC v. Lupin Ltd.*, Civil Action No. 11-7228 (JAP), 2013 U.S. Dist. LEXIS 116988, at *5 (D.N.J. Aug. 19, 2013) (citing *Apple v. Samsung*, Case No.: 11-CV-01846-LHK, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D. Cal. Mar. 27, 2012) (collecting cases)).

The party seeking to amend its contentions bears the burden of establishing diligence. *O2 Micro.*, 467 F.3d at 1366. Further, in determining good cause and diligence, the Court may consider other facts such as:

> (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings.

Warner Chilcott, Civil Action No. 11-7228 (JAP), 2013 U.S. Dist. LEXIS 116988, at *5-6 (citing *Oy Ajat, Ltd. v. Vatech Am., Inc.*, Civil Action No. 10-4875 (PGS), 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012) (collecting cases)).

B. Discussion

1. Diligence

Teva claims that its proposed amended non-infringement contention "is based in part on testimony given during a recent deposition of named inventor Dr. William Schmidt." (Letter from Liza M. Walsh to Hon. Tonianne J. Bongiovanni of 12/3/2018 at 1). The deposition took place on November 14, 2018.[1] Teva argues that during the deposition, Dr. Schmidt "admitted that 'alvimopan' is a different compound than the compound recited by claim 17 of the '030 patent." (*Id*. at 3). Teva claims that Dr. Schmidt's testimony provided it with "sufficient evidence" to support its proposed new non-infringement defense that the active ingredient in its proposed drug product (alvimopan dihydrate) does not infringe the only asserted claim in this case—claim 17 of the '030 patent, and that it diligently sought leave to amend shortly after obtaining the testimony. (*Id*. at 3). In this regard, Teva argues that "[c]ourts in this district have found that 'additional discovery, including depositions, may be necessary to reveal, develop or confirm that sufficient evidence exists to support a party's proposed amendments.'" (*Id*. (quoting *In re Certain Consol. Roflumilast Cases*, CV 15-3375 (FLW), 2017 WL 3816542, at *2 (D.N.J. Aug. 31, 2017) (citing

[1] Teva argues that it timely sought discovery from the named inventors and suggests that Dr. Schmidt would have been deposed sooner had Merck not delayed in responding to its inquiries regarding whether counsel represented the named inventors. (*See* Letter from Liza M. Walsh to Hon. Tonianne J. Bongiovanni of 12/3/2018 at 1). Merck disputes any responsibility, arguing that it informed Teva in its Initial Disclosures that the inventors could be contacted through its counsel. (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 12/10/2018 at 10 n.6). Merck also notes that Teva never issued subpoenas for documents or for depositions of the inventors. (*Id*.)

Helsinn Healthcare S.S. v. Dr. Reddy's Labs, Ltd., CA No. 11-3962 (MLC), 2013 WL 3336859, at *4 (D.N.J. 2013)); *Warner Chilcott Co. v. Lupin, Ltd.*, CA No. 11-7228 (JAP), 2013 WL 4494949 (D.N.J. Aug. 19, 2013)).

Merck, however, maintains that even if Dr. Schmidt's testimony says what Teva claims, which Merck hotly contests, the testimony "implicate(s) only information that was publicly available and known to Defendants[.]" (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 12/10/2018 at 7). In this regard, Merck contends that Teva was aware of the Azodo reference, which states that alvimopan has different CAS numbers for the anhydrous form and the dihydrate form, at least as early as March 2, 2018, as Teva raised the Azodo reference for a different point in its original contentions. (*Id*.) Similarly, Merck argues that "Defendants were clearly aware by March 2, 2018, at the time of their original contentions, that alvimopan can be in an anhydrous or dihydrate form. They knew of the CAS numbers, they knew of the FDA labeling, and they knew of the claims of the '030 patent." (*Id*.) As such, Merck maintains that Dr. Schmidt added nothing to Teva's knowledge; instead, Merck maintains that Teva "deliberately sought to manufacture a new, changed argument by presenting" information that Teva had long been aware of to a third-party fact witness to have him testify about what the information says. (*Id*. at 8). Merck argues that that does not amount to diligence. Indeed, Merck claims that postponing a request to amend contentions "to 'confirm' a theory actually reflects untimeliness and lack of diligence." (*Id*. at 10 (citing *Realtime Data, LLC v. Packeteer, Inc.*, No. 08-0144, 2009 WL 2590101, at *5 (E.D. Tex. Aug. 18, 2009)).

The Court finds that Teva has failed to establish diligence in seeking to amend its non-infringement contentions. While there are certainly instances in which, "additional discovery, including depositions, may be necessary to reveal, develop or confirm that sufficient evidence

exists to support a party's proposed amendments," this is not such an instance. *In re Certain Consol. Roflumilast Cases*, 2017 WL 3816542, at *2. Here, unlike in *In re Certain Consol Roflumilast Cases*, the Court is not dealing with "critical[,]" "non-public" facts that were "unavailable" to Teva prior to Dr. Schmidt's deposition. 2017 WL 3816542, at *1. Similarly, here, unlike in *Warner Chilcott*, the Court is not presented with a request to amend contentions after the production of "internal, confidential documents." 2013 WL 4494949, at *3. Instead, as Merck argues, all of the information Teva needed to raise its proposed new non-infringement contention was available to it at the time it served its original non-infringement contentions.

In March 2018, Teva was certainly aware of the claims of the patent-in-suit, particularly claim 17 of the '030 patent, the only asserted claim in this case. Equally as clear is the fact that Teva was also aware in March 2018 of its proposed FDA label and the Entereg® label. Further, there is no doubt that in March 2018 Teva knew of the Azodo reference, which indicates that alvimopan has different CAS registry numbers for the anhydrous form and the dihydrate form. Indeed, as Merck notes, Teva cited the Azodo reference in its original non-infringement contentions for a different point. Further, in March 2018, Teva knew of the CAS registry, a publicly available compilation of chemical substances organized with numbers. This is the information that substantively forms the basis of Teva's proposed new non-infringement contention.

Dr. Schmidt added nothing of substance to the information already available to Teva. From the flow of his examination, it is clear that Dr. Schmidt went where he was led, revealing nothing of surprise to Teva. Instead, the testimony elicited simply addressed that which Teva already knew. Dr. Schmidt did not reveal any knew information previously unknown to Teva (*see In re Certain Consol Roflumilast Cases*, 2017 WL 3816542, at *1); nor did he testify about Merck's

confidential information. *See Warner Chilcott*, 2017 WL 4494949, at *3. Instead, he testified about public information, available to Teva and clearly in Teva's possession. Teva essentially used Dr. Schmidt's deposition to confirm, in its estimation, its new theory of non-infringement, but such confirmation was unnecessary.

Teva had sufficient evidence on which to base its new theory of non-infringement at the time it filed its original non-infringement contentions. While Teva argues otherwise, the Court finds that a "complete picture" of its proposed new non-infringement defense was available to Teva long before the November 14, 2018 deposition of Dr. Schmidt. *Helsinn Healthcare*, 2013 WL 3336859, at *4. Indeed, Dr. Schmidt played no part in assembling the pieces of Teva's new non-infringement contention puzzle. Teva had already put the puzzle together and was simply hoping to use Dr. Schmidt to glue it in place.

Teva could have easily sought to amend its contentions sooner, but elected to wait. It had the information necessary to develop its new theory of non-infringement since at least March 2018. Teva's failure to include its proposed new non-infringement theory in its original contentions or at least to seek to amend sooner shows a lack of diligence. *See Jazz Pharms., Inc. v. Roxane Labs., Inc.*, Civil Action No. 10-6108 (ES)(MAH), 2015 WL 3822210, *2 (D.N.J. June 19, 2015) (finding party seeking to amend contentions must establish it acted diligently to determine amendment was necessary). As a result, its request to amend fails to meet the standards set forth in L.Pat.R. 3.7.

2. Prejudice

In light of the fact that the Court has determined that Teva lacked diligence in seeking to amend its non-infringement contentions, the Court does not reach the issue of prejudice. The Court does, however, note that fact discovery, except for the depositions of previously noticed fact witnesses, has closed, and the *Markman* hearing in this matter is set to begin next week. *See* Text

Order of 11/27/2018; Docket Entry No. 68. Under these circumstances, the Court is hard-pressed to see how Merck would not be prejudiced by Teva's proposed amended non-infringement contention despite Teva's arguments concerning the dispositive nature of its new non-infringement defense and its claim that the case schedule would not be impacted by the amendment.

III. Conclusion

For the reasons stated above, Teva's request to amend its non-infringement contentions is DENIED. An appropriate Order follows.

Dated: December 11, 2018

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE